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Use of Proficiency Testing as a Tool to Improve Quality in Microbiology Laboratories

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Abstract

Proficiency testing (PT) is a valuable tool for assessing laboratory performance and verifying the accuracy and reliability of test results. Participation is required by the Clinical Laboratory Improvement Amendments (CLIA) of 1988 for each of the microbiology subspecialties (bacteriology, mycobacteriology, mycology, parasitology, and virology), and the regulations include specific PT requirements for each subspecialty. To determine the use and perceived value of PT beyond meeting CLIA requirements, the Centers for Disease Control and Prevention funded a cooperative agreement with the Association of Public Health Laboratories to convene a series of focus groups to query laboratory professionals responsible for PT. The seven focus groups were comprised of 60 laboratory professionals representing large and small clinical laboratories, microbiology subspecialties, and public health. While participants acknowledged the need to perform PT to meet regulatory requirements, many also cited benefits and challenges beyond regulatory compliance.

Introduction

Clinical microbiology laboratory testing plays an important role in the detection, diagnosis, and treatment of infectious diseases and public health disease surveillance. Microbiology laboratories are often the first lines of defense in the detection of antibiotic resistance and in the identification of outbreaks of, e.g., food-borne infection, and are responsible for reporting certain infectious diseases to public health authorities. Therefore, it is critical to ensure high-quality testing and results that are accurate and precise. The Clinical Laboratory Improvement Amendments (CLIA) of 1988 (Public Law 100–578) created uniform quality standards for all laboratory testing to ensure the accuracy, reliability, and timeliness of patient test results regardless of where the testing is performed (1). The regulations that implemented the law were published in the Federal Register on 28 February 1992 (2) and were updated in the Federal Register on 24 January 2003 (3). These requirements for laboratories and other testing sites are based on the technical complexity of the testing performed within three test categories specified in the regulations: waived, moderate complexity, and high complexity. All laboratories must have the appropriate CLIA certificate issued by the Centers for Medicare & Medicaid Services (CMS) for the testing they perform. Microbiology laboratories that conduct moderate- or high-complexity (non-

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waived) testing, which includes most microbiology laboratories, need to meet the standards in the regulations for these testing categories and must have a CLIA Certificate of Compliance (CoC) or a CLIA Certificate of Accreditation (CoA). CoCs are issued to laboratories by CMS through individual state agencies, whereas CoA laboratories are voluntarily accredited by a CMS-approved professional organization. A list of approved accrediting organizations under CLIA can be found at http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/AOList.pdf. Accredited laboratories meet the accrediting agency's requirements as a mechanism for satisfying the requirements for CLIA certification. Although these requirements may not be identical to those in the CLIA regulations, overall, they are equal to or more stringent than CLIA at the condition level. Table 1 shows the number of CLIA certificates issued to each of the microbiology subspecialties, as of December 2012, identified in the Online Survey, Certification and Reporting (OSCAR) database maintained by CMS. It includes microbiology laboratories inspected by CMS, those that are accredited, and microbiology laboratories in the CLIA-exempt states of New York and Washington.

CLIA PT Requirements for Microbiology

Proficiency testing (PT) is a means of external quality assessment that is one of the main facets of the CLIA quality system for non-waived testing. It is a valuable tool for assessing laboratory performance and verifying the accuracy and reliability of test results. CLIA mandates that all laboratories that perform certain non-waived testing participate in a PT program approved by CMS. For clinical microbiology PT, laboratories are sent multiple simulated clinical specimens for analysis using the laboratory's established methods for testing patient specimens. The test results are submitted to the PT program for analysis, and the laboratory's individual performance is graded using specified CLIA scoring criteria with either a peer group or an assigned target determined by selected referee laboratories. PT permits a laboratory to assess its performance and provides confidence that the laboratory's performance conforms to quality expectations required for patient care. Studies have shown the value of an external quality assessment program, such as PT, as an indicator for maintaining and improving the quality of laboratory results (4–7).

Microbiology laboratories conducting non-waived testing need to meet general PT requirements, which include the following:

- Enroll in a CMS-approved PT program for each specialty and subspecialty for which testing is performed. A list of CMS-approved PT programs can be found online at http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/ptlist.pdf.
- Analyze at least five PT samples per testing event.
- Obtain an 80% correct score on each testing event to achieve satisfactory performance.
- Perform satisfactorily on two out of three testing events for successful performance.
- Test PT samples in the same manner as testing is performed for patient specimens.

- Perform PT for the primary method, test system, or examination used for patient testing.
- Do not send PT samples or portions of samples to another laboratory for analysis.
- Do not engage in inter-laboratory communication pertaining to PT until after the due date for reporting results to the PT program.

Since microbiology does not have analytes as indicated in other specialties, CLIA requires PT for each subspecialty of microbiology: bacteriology, mycobacteriology, mycology, parasitology, and virology. Table 2 lists the CLIA PT requirements for the microbiology subspecialties.

For tests not specified in the PT regulations, such as fungal antigen detection, antifungal susceptibility testing, and parasite antigen detection, CLIA requires laboratories to ensure accuracy at least twice annually for all tests performed. One way this can be accomplished is by enrolling in a voluntary PT program for the test. Modules that generally have fewer samples or fewer shipments per year that require PT are offered by many PT programs. Test results for these modules are scored by the programs and returned to participants, who can compare scores to verify the accuracy of the testing. Another way in which laboratories can check the accuracy of testing when PT is not required is to split patient specimens with another laboratory that offers the same test. The laboratory director can review and compare results for acceptability. Laboratories can also perform in-house blind testing of samples with known organisms or use photographic images from a reference source to verify the identification accuracy of tests when PT is not required or available. CMS provides a brochure (CLIA Proficiency Testing Do's and Don'ts) that is available at http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAbrochure8.pdf.

Steps of the PT Process

Enrollment

The first step in the PT process should begin with a review of the PT requirements for each subspecialty of microbiology shown in Table 2. Once the tests performed by the laboratory are determined, the laboratory needs to enroll in a CMS-approved PT program that offers modules for those tests. Laboratories may need to enroll in more than one PT program to fit their service needs. Some PT programs provide individual modules for specific culture types, such as urine or throat cultures. These types of modules are useful for small laboratories, such as physician office laboratories (POLs) that only perform cultures on limited specimen types. The programs will assist laboratories with selecting the appropriate enrollment options, if needed. Once enrolled, PT programs will submit laboratory enrollment information to the CMS PT database. On occasion, laboratories may wish to change PT programs due to factors such as module cost, module configuration, or number of peer participants. They may not randomly change from one program to another but must enroll and participate in a PT program for 1 year before changing to a new program. For laboratories operating under a new CLIA certificate or adding a new test or specialty, enrollment in PT should occur as soon as possible.

Sample Processing and Testing

Some PT programs will provide information on the sample source and clinical history. For many laboratories, this information is essential because it will dictate which media to use and/or which test to perform when microbial identification is required. For some PT, sample preparation may be necessary before testing, as PT programs use different types of samples depending on the test to be performed, and they are often shipped as a powder or concentrate that requires reconstitution or dilution. Lyophilized microorganisms may have different behavioral properties than their live counterparts, and errors in sample preparation can lead to inaccurate test results. In many cases, culture of organisms is not required to perform antigen-screening tests, so programs may send out non-viable organisms for antigen-testing PT. In addition, because it is sometimes not cost-effective for PT programs to provide samples that can be used for multiple tests, such as culture, antigen detection, PCRs, or other molecular tests, as would occur with patient testing, PT samples that can be used only for a particular method of testing are often provided.

After preparation, PT samples should be tested in the same manner as patient specimens to the extent possible, even if the samples do not look like actual microbiology specimens and require processing that would not be done for patient specimens. Laboratories should avoid repeat testing of PT samples when patient specimens are only tested once, and PT should be rotated among all the testing personnel who are involved in patient testing.

Results Reporting

When testing PT samples, laboratories are instructed to perform all testing and report results as they normally would on a patient specimen; laboratories should report PT results for organism identification to the same level that they would for patient testing, e.g., “*Escherichia coli*” versus “Gram-negative organism present.” As a result, microbiology PT can be challenging and confusing with respect to the reporting of different identification levels. For instance, one laboratory may report growth/no growth if that is their practice for reporting patient results, whereas another laboratory may report the same challenge organism to the genus or species level, resulting in numerous possible correct answers. Under other circumstances, laboratories may vary the level of organism identification based on the culture source, such as reporting only to the genus level on urine cultures. PT programs provide an attestation statement that must be signed by the analyst and the laboratory director or designee certifying that PT samples were tested in the same manner as patient specimens, including reporting the microorganism identification to the same level and in the same way that results are reported for patient specimens.

After testing, PT result forms or on-line result submissions should be carefully reviewed to avoid common clerical or calculation errors. All results should be submitted by the date specified by the PT program. Records documenting the handling, preparation, processing, and examination and each step in the testing and reporting of PT results must be maintained for a minimum of 2 years from the date of each PT event. Regulatory inspectors may request PT records and raw data used to generate results, and the information must be accessible and retrievable within a reasonable time during a laboratory inspection.

Scoring and Evaluation of Results

After PT programs have analyzed all the results for an event, they will send each laboratory their scores, including a summary or evaluation for each test in the PT event. The evaluations provide details on the performance of each test system used by the PT program's participating laboratories. When each laboratory receives its results, the laboratory should compare them with the inter-laboratory comparisons provided in the summaries or evaluations by the PT programs. When a laboratory submits incorrect PT results or does not receive a passing score on a graded event, it should review the results submitted to identify the cause of any errors, including clerical or transcription mistakes. In cases of unsatisfactory performance or PT problems, the laboratory needs to document the investigation, corrective action, and ongoing monitoring.

In microbiology, unsuccessful PT performance means failure to attain a satisfactory score for a subspecialty or specialty for two consecutive or two of three consecutive testing events. If this occurs in a CoA laboratory, the appropriate accreditation organization would instruct the facility to undertake training or obtain technical assistance. For a CoC laboratory with initial unsuccessful PT, the CMS regional office may allow the state agency to request that the laboratory undertake training and obtain technical assistance, provided the laboratory has a good history of compliance with CLIA and there is no immediate jeopardy to patient testing, no history of PT referral, and no current significant quality problems. The laboratory must have also agreed to correct the problem causing the unsuccessful PT. Repeated, unsuccessful PT performance for the same subspecialty or specialty may result in the laboratory no longer being allowed to perform the failed testing in the affected subspecialty. After a laboratory has identified the reason(s) for the unsuccessful performance and corrective action has been taken and documented, the laboratory must perform two consecutive PT events successfully for re-instatement. As with other PT documents, if any corrective actions are taken as a result of an unsatisfactory or unsuccessful PT score, the records should be maintained for 2 years.

CLIA PT Referral

Sending all or part of a PT sample to another laboratory for testing or communication with another laboratory about PT results is considered PT referral even if patient specimens are routinely sent out for additional or confirmatory testing. PT result report forms may contain the option to select "test not performed" or "would refer" in cases where actual patient specimens would be sent to another laboratory for confirmation or identification testing. If a laboratory receives PT samples from another laboratory for testing, they should notify the appropriate inspecting agency (regional office, state agency, or accreditation organization) and should not perform testing on the samples. Over time, CMS has investigated numerous PT referral cases. If a finding of PT referral is confirmed, serious sanctions are taken by CMS against the laboratory, laboratory director, and laboratory owner. The possible penalties include loss of the laboratory's CLIA certificate for at least 1 year, prohibition of the director from directing a laboratory for 2 years, and prohibition of the laboratory owner from owning or operating a laboratory for 2 years.

An amendment to the CLIA law, the Taking Essential Steps for Testing (TEST) Act of 2012, H.R. 6118 (8), signed by the president in December 2012, is intended to resolve the longstanding issue of CLIA enforcement due to unintentional PT referral. The TEST Act clarifies that sending a PT sample to another laboratory for analysis is prohibited, despite the requirement that PT samples be treated like other patient specimens. The act gives the Secretary of Health and Human Services discretion as to whether to revoke a laboratory's CLIA certificate for 1 year in the event of a PT referral violation and additional discretion to substitute intermediate sanctions in lieu of a mandatory 2-year ban on a laboratory director and laboratory owner if the CLIA certificate is revoked. Under this change, CLIA certificate revocation for a laboratory may become optional rather than mandatory. Rulemaking to define when the discretion will be applied and when revocation will be imposed is forthcoming from CMS. In the meantime, the TEST Act does not change the requirement that laboratories be prohibited from sending PT samples or portions of PT samples to another laboratory and that any laboratory receiving a PT sample from another laboratory must report the receipt to CMS.

Use and Value of PT Beyond Meeting Regulatory Requirements

In addition to using PT as a way to meet regulatory requirements, microbiology laboratories can realize other benefits. To obtain the perspective of laboratory professionals on the value of PT, the Association of Public Health Laboratories (APHL) conducted an informal survey of approximately 30 attendees at the Clinical Laboratory Management Association (CLMA) May 2010 ThinkLab meeting. Survey questions addressed the use of PT beyond meeting regulatory requirements for the purpose of improving the quality of testing, the benefits and challenges of PT, and satisfaction with services offered by PT programs. The CLMA survey results prompted a CDC-funded cooperative agreement with APHL to obtain additional information on the challenges and benefits of PT beyond its use in meeting regulatory requirements (9).

Focus Group Participant Selection

As stated above, CDC funded a cooperative agreement with APHL to convene a series of focus groups to query laboratory professionals responsible for PT in their facilities as to their use of PT and its perceived value. To our knowledge, this laboratory perspective had not previously been explored; the focus group format allowed the topic to be investigated through questions developed around the use of PT. The individuals selected for the focus groups were primarily laboratory professionals with supervisory or managerial status and decision-making responsibilities related to PT. A total of 60 participants were recruited from hospitals, independent public health laboratories, and POLs located within an approximately 50-mile radius or less than one driving hour from one of the focus group sites (Atlanta, GA; Houston, TX; Boston, MA; and New Orleans, LA). Participants from four facility categories were targeted for inclusion in the focus group sessions: large multi-specialty laboratories, small multi-specialty laboratories, public health laboratories, and microbiology laboratories. All categories included facilities that performed microbiology testing as part of their test menu, but the specific microbiology laboratory category consisted of laboratory directors or personnel who worked specifically in microbiology. One microbiology focus group

consisting of six participants was held in Houston, TX, and another group consisting of 12 participants coincided with the 111th General Meeting of the American Society for Microbiology in New Orleans, LA. Eleven public health laboratories were identified through the APHL database and recruited from the northeast region for a focus group in Boston, MA. This group consisted of both local and state public health laboratories that do not function as part of a university hospital system and included a food/agricultural laboratory in Florida.

For the purpose of the focus groups, large laboratories were defined as those having a yearly test volume greater than the median OSCAR database volume of 300,000 tests. Small laboratories were defined as those having a yearly test volume less than the median OSCAR database volume of 300,000 tests per year. Regardless of their test volumes, microbiology laboratories were identified through OSCAR as those laboratories that conduct bacterial culture identification.

Table 3 shows the participant demographics of the focus groups' four facility categories. There were 13 participants representing small laboratories, 18 participants representing large laboratories, 18 participants representing microbiology laboratories (both large and small), and 11 participants representing public health laboratories, some of which performed microbiology testing. Of the 60 facilities, 9 (15%) self-identified as CMS CoC laboratories; the remaining 51 (85%) reported being accredited by CMS-approved accrediting organizations. Five (46%) of the 11 public health laboratories identified themselves as CoC laboratories. Five (39%) of the 13 small laboratories were classified as POLs; of those five POLs, 4 self-identified as CoC laboratories. Attempts were made to recruit both large and small laboratories to include both CoA and CoC laboratories. However, smaller laboratories tended to be more difficult to recruit due to limited staff availability.

Focus Group Findings

In all focus groups conducted, participants shared information concerning the relationship of PT to overall quality assurance, including the analytical process, personnel competency, and satisfaction with PT program services. Table 4 summarizes the responses provided by the focus groups regarding the primary benefits of performing PT beyond meeting regulatory requirements. In these responses, participants stated that the most important benefits of PT included the following:

- Provides value as a quality indicator
- Instills confidence in the quality of a laboratory's performance
- Provides educational opportunities
- Serves as a tool for evaluation of staff competency
- Allows peer group comparisons of test results

In addition to the benefits of PT, participants identified many challenges with the CLIA requirement to treat PT samples the same as patient specimens. Concealing the identity of PT samples is difficult, since the samples often do resemble actual patient specimens, and PT samples may require more instruction on handling, testing, and reporting results than

would be required for patient tests. Table 5 summarizes the challenges focus group participants identified as significant with respect to PT. For microbiology, most agreed that the quality of photo-micrographic images is poor in bacteriology and parasitology, particularly for Gram stains. Image quality and size may be distorted, although it was their opinion that images do not adequately measure testing proficiency. Many of the microbiology respondents observed that while Gram stains of patient specimens would be examined by microscopically viewing multiple fields before reporting results, Gram stain PT often relies on observation of one photo-micrographic image. Most questioned the value of identifying any organism by one photomicrograph or one slide field with no other pertinent information, which is not consistent with how they would approach Gram stain examination in the laboratory.

While there were many instances in which the perception and the use of PT were similar for all groups, issues from large facilities, microbiology laboratories, and public health laboratories mainly focused on overall PT program requirements and services. In these laboratory types, the PT process was facilitated due to increased numbers of staff, and PT was viewed as an educational opportunity rather than just a regulatory requirement. Larger laboratories, however, expressed concern over the slow response of PT programs to make PT available for new technologies. The smaller facilities tended to focus on meeting the CLIA PT requirements while fitting the PT samples into their routine without jeopardizing patient testing. Meeting the requirements of PT testing was seen as an additional strain at these sites. Smaller facilities noted the value of PT in competency assessment and education but did not utilize it as an educational tool to the same extent as the larger facilities. Regardless of facility size, the majority of participants stated that the most important benefit of PT is its value as a quality indicator, and as such, they acknowledged that PT increases confidence in the quality of a laboratory’s performance.

Although participants valued PT as an integral part of a laboratory quality control program, throughout the focus group discussions, recommendations were made for improvement. Table 6 summarizes these recommendations for PT improvement in relation to PT cost, PT sample/module configurations, and PT reporting. To cut back on costs, participants suggested the ability to purchase customized modules that would allow laboratories to choose PT tests as a customizable group.

In addition to the general questions, the microbiology laboratory and public health laboratory focus group participants were asked several questions on microbiology-specific topics, including PT background/patient information provided with the samples, PT microorganism identification reporting-level consistency, PT for individual microbiology tests rather than combined scores for each subspecialty, and the possible impact of increasing the number of microbiology PT challenges beyond what is now required by CLIA. Most participants felt that the background information provided with the PT samples was comparable to the information provided with patient specimens. Several participants stated they would prefer to have more information but cited only name and sex as needed to enter the samples into their system. To ensure that the reporting of PT results for organism identification is consistent with the level of reporting for their laboratories, most participants reported that the PT instructions require that PT results be reported to the same level as for

patient specimens. Since the workflow mirrors patient testing processes and procedures, PT samples are reported at the same level as patient specimens. Currently, a combined subspecialty score is provided by PT programs to laboratories for microbiology. Participants agreed that having an individual score for each testing procedure in addition to the combined score could identify areas in need of targeted training for performance improvement. Several microbiology laboratory participants supported having more PT susceptibility testing challenges to ensure confidence in patient results. An additional benefit of PT noted by many microbiology focus group participants is the use of PT samples as an important source for stock cultures of organisms that are not commonly identified in their facility. After the PT has been completed, the organisms are then available for use in training and competency assessments. Lastly, most participants would welcome the challenge of organisms that are more difficult to identify or less frequently seen and fewer negative samples in microbiology PT.

Conclusion

Based on the findings from these focus groups conducted by APHL, it appears that many laboratories use their PT results internally for quality improvement, in addition to fulfilling a regulatory requirement. Many non-regulatory benefits were expressed in common across focus groups, including the use of PT to ensure confidence in the quality of a laboratory's performance, its use and value in demonstrating staff competencies, and education and training of testing personnel. However, participants also mentioned the challenges of PT, including the CLIA requirement to treat PT samples the same as patient specimens; administrative issues, such as staff time and PT program costs; and PT sample quality, including poor photographic images. In conclusion, since laboratories already pay for PT materials, the use of PT for quality improvement purposes has the potential to further improve laboratory quality at no additional cost to U.S. clinical laboratories.

Looking Ahead

Since the CLIA PT regulations have not been revised since they were implemented in 1994, CMS and CDC are now developing a proposed rule to update the PT requirements for all laboratory specialties. In September 2010, the Clinical Laboratory Improvement Advisory Committee (CLIAC), charged with providing scientific and technical advice on issues pertaining to CLIA and laboratory quality to the Department of Health and Human Services, including the three government agencies (CDC, CMS, and FDA) with shared responsibility for the CLIA program (10), made 23 recommendations addressing possible changes to the CLIA requirements for PT, which can be found at http://wwwn.cdc.gov/cliacpdf/CLIAC0910.pdf. The recommendations covered all laboratory specialties, including changes to microbiology PT. Levels of service, required categories of tests, major groups of microorganisms included in PT, Gram stain PT, mixed-culture requirements, antimicrobial susceptibility testing, direct antigen testing, and monitoring microbiology performance over time were all addressed in the CLIAC recommendations and are being considered as the proposed regulatory changes are developed.

The focus group findings prompted APHL and CDC to develop an anonymous online survey that will be disseminated later this year (2013) to all laboratories that are required to perform PT under CLIA. The target laboratories include 20,500 CoC laboratories and 16,800 CoA laboratories. The primary goals are to better understand the perceived benefits and burdens of performing PT and to conduct a systematic analysis in order to understand laboratory PT practices, to identify ways that practices could be better promoted, and to identify laboratories that would benefit from receiving additional information.

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Table 1

Total number of CLIA certificates issued for the microbiology subspecialties[a]

Subspecialty	No. of certificates[b]
Bacteriology	26,739
Mycobacteriology	2,909
Mycology	20,930
Parasitology	19,973
Virology	9,346

[a] Data obtained from CMS OSCAR database (17 December 2012).

[b] Including laboratories in exempt states.

Table 2

CLIA PT requirements for microbiology subspecialties

Subspecialty	Minimum no. of PT samples/event	No. of events/yr	Stain and/or preparation	Antigen testing	Organism identification	Susceptibility testing
Bacteriology	5	3	Gram stain	Direct-antigen techniques to detect an organism	Isolation and identification of aerobic and/or anaerobic organisms	Antimicrobial susceptibility tests
Mycobacteriology	5	2	Acid-fast stains	None	Isolation and identification of *Mycobacterium tuberculosis* and/or all mycobacterial species	Antimycobacterial susceptibility tests
Mycology	5	3	None	None	Isolation and identification of yeasts, dermatophytes, and/or fungi	None
Parasitology	5	3	Wet mount, pinworm preps, formalinized specimens, PVA fixed, and blood smears	None	Presence or absence of parasites by wet mount and/or pinworm prep and/or identification of parasites using concentration preparations and/or permanent stains	None
Virology	5	3	None	Direct detection of viral antigen or structures	Isolation and identification of viruses	None

Table 3

Focus group participant demographics

	No. fulfilling criterion			
Criterion	**Large laboratories**	**Small laboratories**	**Microbiology laboratories**	**Public health laboratories**
State Public Health Laboratory	0	0	0	8
Local Public Health Laboratory	0	0	1	2
State Agricultural Laboratory	0	0	0	1
Manufacturing Industry Laboratory	1	0	0	0
Independent/Commercial Laboratory	1	2	0	0
Physician Office Laboratory	2	5	0	0
University/Medical School Laboratory	1	0	4	0
Large Hospital/Clinic Laboratory	13	6	13	0
CLIA Certificate of Compliance	0	4	0	5
CLIA Certificate of Accreditation	18	9	18	6

Table 4

Proficiency testing benefits beyond meeting regulatory requirements

Topic	Benefits	Examples
PT use in quality management	Competency, education, and training	• Results can be used to identify staff that may require more training. • Remaining samples can be used to assess staff competencies. • Remaining samples can be used for staff education and training. • Samples can provide an important source of rarely seen organisms.
	Quality evaluation and improvement	• Scores can indicate areas where improvement may be needed. • Scores can be used in defense of quality of testing and results with upper management. • Scores can be used to defend the quality of laboratory results when occasionally challenged by a clinician.
	Assessment of methodology/ instrumentation	• Remaining samples can be used to test the accuracy of various systems, validate new instrumentation, verify accuracy with laboratory-developed tests, and troubleshoot analyzers. • Summary reports can be used to obtain information on PT performance to change or recommend a change in methodology or instrument. - Compare instruments when results are peer grouped - Identify methodologies/instrumentation used by the majority of laboratories
	Trending	• Results can be used to monitor trends in performance over time. • Trends can be used to identify a problem before it becomes significant.
PT program satisfaction	Turnaround times	• Time from PT sample receipt to submission of test results to PT program was adequate to perform and report testing.
	Technical advice	• Programs provide educational challenges with added information. • Programs provide additional information on their websites regarding ungraded challenges. • Technical experts were knowledgeable.

Table 5

Proficiency testing challenges experienced by clinical laboratory professionals

Topic	Benefits	Examples
PT sample identification/handling	PT samples treated the same as patient specimens	• PT samples do not physically resemble patient specimens, which makes it difficult to handle and treat them the same. • Samples require more instruction on handling and safety precautions, reconstitution, testing, and reporting results than patient specimens. • Additional documentation required for PT samples may lead to potential for transcription errors. • Entering PT information into an electronic laboratory information system (LIS) may result in errors in computation and conclusions for non-analytical purposes.
PT use in quality management	Total testing process evaluation	• PT has limited value in the pre- and post-analytic phases of testing.
	Methodology/instrumentation assessment	• Determination as to which analyzer should be designated for analysis and for reporting when the test is performed on multiple analyzers may result in additional tracking and paperwork.
	Competency, education, and training	• Fear of failure is a concern. • Staff are held accountable for the results by management, and consequences of failure can be serious for laboratorians.
	Trending	• PT results at the extreme high and low ends of the analytical range may result in data that are less useful for methodology and instrument monitoring. • Trending is not useful in microbiology because samples are repeated less frequently.
Technical challenges	PT sample unavailability	• Developing an alternative PT program when samples or analytes are not available commercially can be challenging. • There is sometimes a lag time until the PT program provides tests for new instruments or methodologies.
	Matrix effect	• PT sample matrices are unlike patient specimens and can lead to testing issues.
	Ungraded PT challenges	• Corrective action with documentation is necessary and involves extended staff time.
Administrative challenges	PT program costs	• Expense of PT can be difficult to justify in the budget. • Sometimes it is necessary to purchase multiple modules to cover all analytes tested.
	Staff time	• PT is time-consuming and difficult to incorporate into daily workload.

Topic	Benefits	Examples
		• Extensive time is needed for documentation, ordering PT, reporting results, managing paperwork volume, and clerical review. • LIS may handle PT data differently than patient data, and extra time is needed to process it.
PT program satisfaction	PT sample quality/quantity	• Poorly stained slides • Distorted images in photomicrographs • Quantity not enough for a repeat test • Complex reconstitution instructions • Lack of sample source information with microbiology samples • Susceptibility testing issues due to number of passes of an organism
	PT reporting unit consistency	• PT reported in units that are different from those used to report patient specimens • Need to perform unit conversions • PT program changes reporting units
	PT reporting format	• Different reporting format for each PT program • Process different from how patient specimens would be reported
	Customer service	• Automated telephone response system does not provide opportunity to talk with a live person. • Difficult to reach a technical expert
	Turnaround times	• Unable to rerun labile samples

Table 6

Recommendations for improvement

Topic	Examples
PT cost	• Provide customized modules.
Sample/PT modules	• Provide PT samples that more closely resemble patient specimens. • Decrease number of negative samples. • Provide more complex organism samples. • Resolve CLSI and FDA susceptibility testing breakpoint differences.
PT reporting	• Reduce paperwork. • Provide uniform reporting procedures across modules.